K122305 (pg 1/2)

3. 510(K) SUMMARY

1. Applicant/Sponsor:

Corin USA
10500 University Center Drive
Suite 190
Tampa, Florida 33612
Establishment Registration No.: 1056629

NOV 2 1 2012

2. Contact Person:

Diana L. Martone
Regulatory Affairs Associate
Corin USA
813-977-4469
diana.martone@coringroup.com

3. Proprietary Name: Corin Trinity Acetabular System with Trinity-i Acetabular Shells

4. Common Name: Hip Prosthesis

5. Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353, Product Codes LZO, MEH)

6. Legally Marketed Devices to which Substantial Equivalence is claimed:

- Corin Trinity Acetabular System (K093472)
- Corin Trinity Acetabular System with HXLPE Liners(K110087)

7. Device Description:

The Trinity Acetabular System is a modular acetabular cup system consisting of a press fit, titanium alloy shell, ultra-high molecular weight polyethylene (UHMWPE), highly cross-linked polyethylene (HXLPE), vitamin E highly cross-linked polyethylene (ECiMa) acetabular liners in neutral offset, +4mm offset, +4mm oblique, neutral 4mm EPW, BIOLOX *delta*™ ceramic and CoCr modular heads and titanium femoral stems. The acetabular shells are coated with a rough titanium plasma spray with an additional top layer of electrochemically deposited calcium phosphate (Bonit™).

The purpose of this submission is to add Trinity-i acetabular shells in sizes with a larger inner diameter, but with the same outer diameter, to accommodate a larger liner and corresponding head size to the Trinity Acetabular System.

The Trinity Acetabular System is intended for use in total hip arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged hip

joint articulation where there is evidence of sufficient sound bone to seat and support the components.

8. Intended Use / Indications:

   The indications for the Trinity Acetabular System as a total hip arthroplasty include:

   - Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
   - Rheumatoid arthritis
   - Correction of functional deformity
   - Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

   The Trinity Acetabular System is intended for cementless, single use only.

9. Summary of Technologies/Substantial Equivalence:

   The additional components of the Trinity Acetabular System are exactly the same as the predicate devices in terms of intended use, indications for use, and materials; and are similar in sizes, design and performance. Based on these similarities, the additional components of the Trinity Acetabular System are believed to be substantially equivalent to the predicate devices.

10. Non-Clinical Testing:

    Non-clinical testing conducted to demonstrate substantial equivalence includes: determination of shell stiffness, effect of the coating process on shell taper form, and the effect of shell deformation on HXLPE and ECiMa liners. Bench testing of the Trinity titanium shells and characterization and testing for the coating was included in previous submissions for the Corin Trinity Acetabular System (K093472 and K110087).

11. Clinical Testing:

    Clinical testing was not necessary to determine substantial equivalence between the additional components of the Trinity Acetabular System and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Dated: November 21, 2012

Corin USA
% Ms. Diana L. Martone
Regulatory Affairs Associate
10500 University Center Drive
Tampa, Florida 33612

Re: K122305
Trade/Device Name: Trinity Acetabular System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO, MEH
Dated: November 9, 2012
Received: November 13, 2012

Dear Ms. Martone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K122305

Device Name: Trinity Acetabular System

Indications for Use:

The indications for the Trinity Acetabular System as a total hip arthroplasty include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Trinity Acetabular System is intended for cementless use only.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna Asundi
for (Division Sign-Off)
Division of Orthopedic Devices

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